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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,587	03/21/2002	Tsutomu Okubo	1422-0520P	4925

2292 7590 06/04/2004

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,587

Applicant(s)

OKUBO ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2002.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) 1-7 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/20/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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**Acknowledgement:** The Preliminary Amendment filed March 21, 2002 and the Information Disclosure Statements filed June 21, 2002 and March 17, 2004 are acknowledged.

## **DETAILED ACTION**

### **Status of Claims**

Claims 1-7 are pending following applicant's amendment.

### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-2 are rejected under 35 USC 102(b) as anticipated by Moroe et al (US 4, 634, 588).

The claims are directed toward a composition comprising theanine, said composition for suppressing craving for smoking characterized as withdrawal symptoms caused by prohibition or moderation of smoking.

Patent '588 teaches a composition comprising theanine (col 2, lin 1-14 and col 12, lin 62-65).

Claims 1-2 are anticipated by Patent '588.

### **Claim Rejections - 35 USC § 103**

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Moroe et al (US4, 634, 588) further in view of the combination of Kakuda et al (US5, 736, 575) and Blaum et al (US 6, 132, 724).

The claims are drawn toward a composition comprising theanine (also known as gamma-glutamyl ethylamide). The claims are also drawn administering the composition to humans for suppressing craving for nicotine, alleviating or eliminating withdrawal symptoms caused by moderation of smoking, that the composition is in a formulation suitable for absorption via the oral mucosa and is suitable as a food composition.

3. Moroe et al (Patent '588) discloses a composition in the form of chewing gum comprising amino acids selected from the group consisting of dl-alanine, l-isoleucine, glycine, threonine, l-theanine, l-valine and l-lysine mono hydrochloride (col 12, lin 15-65). Patent '588 discloses that the composition can be used in combination with other ingredients such as extracts from tea leaves (col 3, lin 14-20) and is applicable to oral hygiene products such as tooth paste, candies, food additives such as fish/meat odor masking agents (col 3, lin 10-20). Patent '588 does not disclose the administration of a theanine composition in the form of tablet or capsule for suppressing craving for smoking or eliminating withdrawal symptoms ensuing by the prohibition or moderation of smoking.

4. Kakuda et al (Patent '575) discloses that theanine in the effective concentration or amount when administered to subjects as an oral agent affects the brain waves and has excitement acceleration activity in subjects (abstract, col 3, lin 45-50; col 1, lin 25-35 and col 6, lin 40-47). Patent '575 also discloses that theanine is contained in tea; similar to the disclosure

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in applicant's specification (spec at page 6, lin17-19). Patent '575 does not disclose the specific oral agent or formulation in which theanine is administered, does not disclose the use of theanine for suppressing or alleviating withdrawal symptoms caused by prohibition or moderation of smoking.

5. Blum et al (Patent '724) discloses a composition comprising theanine (col 75, lin 20-40). Patent '724 discloses that the composition in appropriate cocktail is useful for the treatment of various disorders in humans known as "reward deficiency syndrome disorders", such disorders including but not limited to tobacco use (col 21, lin 52-55, col 22, lin36-50) that have been shown to have some genetic predispositions (col 26, lin 10-15 and col 57 and 58, Table 2). Patent '724 discloses other anti-craving compositions that are currently commercially available in capsule formulations, including Nicarest (anti-smoking agent).


6. One of ordinary skill would be motivated to prepare a composition comprising theanine by isolating the compound from tea leaves and make such composition in the form of capsules that can be made commercially available for use as smoking cessation agent. One of ordinary skill would expect to obtain an effective anti-craving composition as an aid to smoking cessation at low cost because tea leaves or plants are relatively cheap source of theanine, as disclosed in the prior art cited. Moreover, one of ordinary skill would expect that making the theanine composition in capsule formulation can provide convenient and easy- to- take medication to a large number of smokers who wish to quit the habit. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### Correspondence

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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